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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS

AND INTERFERENCES

Ex Parte HANS SMOLA *and* GILBERTO NEPOMUCENO

Appeal 2010-002821
Application 10/596,159
Technology Center 1600

Oral Hearing Held: April 12, 2011

Before RICHARD M. LEBOVITZ, FRANCISCO C. PRATS, and STEPHEN G. WALSH, *Administrative Patent Judges.*

APPEARANCES:

ON BEHALF OF THE APPELLANT:

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The above-entitled matter came on for hearing on Tuesday, April 12, 2011, commencing at 1:15 p.m., at the U.S. Patent and Trademark Office, 600 Dulany Street, Alexandria, Virginia, before Cynthea Sydnor-Thomas, a Notary Public.

PROCEEDINGS

JUDGE LEBOVITZ: Okay, we're on record. We are Appeal No. 2010-002821, which is Application No. 10/596,159, is that correct?

MS. LYNCH: Yes.

JUDGE LEBOVITZ: Okay. If you can, introduce yourself and begin when you're ready, and you'll have about 20 minutes.

MS. LYNCH: Sure. Good afternoon. My name's Rachel Lynch. As you said, I'm here for Appellants for Serial No. 10/596,159. So this Appeal includes just one obviousness rejection, and, as I'm going to argue and as I hope you will agree, that the rejection is improper as a matter of fact and law. So before I get into the actual arguments, I'd like to walk you through a little bit about our invention.

Specifically, Appellant has discovered that combining specific amounts of proline and arginine synergistically enhance wound healing. So as discussed in the Specification, proline's provided in the nutritional composition in an amount that helps facilitate halogen synthesis.

Now, arginine has also been found to help with wound healing, as discussed in the specification, but Appellant has found that simply combining these two ingredients together doesn't necessarily optimize wound healing for the patient or the consumer of the composition. Instead, arginine is a metabolic precursor for nitric oxide which acts as a vasodilator and enhances growth hormone secretion. So as is discussed in-depth in the Specification, it's not optimal for critically ill patients to be exposed to high amounts of nitric oxide, so Appellant has found that if you include specific amounts of proline and arginine you can optimize and create a delicate balance of the two to administer to these patients for wound healing.

JUDGE LEBOVITZ: I thought I heard you use the term synergistic?

MS. LYNCH: Yes.

JUDGE LEBOVITZ: Do you have any evidence in the Specification or by declaration of synergy?

MS. LYNCH: We do not. We do have an experimental example in the Specification that shows a drastic benefit when a consumer is administered specific amounts of proline. We do not have in the Specification a specific example of the specific amounts combined.

So Appellants are going to argue that the skilled artisan would have no reason to combine *Gray* and *McEwen* because *Gray* teaches away from the combination of *McEwen* as well as the present claims. Moreover, references must be considered as a whole, and those portions that teach away from the claimed invention must be considered. For example, the Examiner cites *Gray* for the disclosure of a composition for wound healing having protein lipids, carbohydrates, and proline and arginine. As discussed in the Specification, however -- I'm sorry, in Appellants' Appeal Brief, *Gray* expressly states that at least 3 percent of the total calories must be present from arginine and that enhanced wound healing with arginine is believed to be provided at quantities greater than 3 percent of the total calories.

Now, in the disclosure of *Gray*, they go even further to say that the composition should have a "high arginine content and that in choosing the protein source the present invention maximizes the natural availability of arginine." So repeatedly throughout *Gray* they're saying you have t have a minimum of 3.0, and even greater than that is where you find enhanced wound healing. So this is in direct contrast to what Appellant is saying, which is that not more than 1.8 percent of the total calories should be

provided by arginine. And this isn't just a random limitation for arginine. It actually has a physiological benefit, as stated previously, in that it's a metabolic precursor to nitric oxide which is -- can actually provide complications for wound healing instead of aiding in wound healing.

So instead of having, you know, 3 percent or more, Appellants are specifically saying you need to have a low amount of arginine and we require not more than 1.8 percent. So we have purposely limited the amount of arginine that can be present in our nutritional compositions. *Gray* is not at all concerned with potential physiological disadvantages and, as I said, actually requires maximizing the amounts of arginine provided. So in effect, *Gray* would lead the skilled artisan down a path that is divergent from that taken from Appellant in this case, that is, that *Gray* requires maximizing or at least 3 percent. We require no more than 1.8, which is almost half that and required to be less than that.

JUDGE LEBOVITZ: Do you have any disclosure in your Specification about why those amounts were chosen? I know you're alluding to it or talking about it, but is that disclosed in the Spec?

MS. LYNCH: A specific reason why?

JUDGE LEBOVITZ: Yes.

MS. LYNCH: Is not disclosed. Generally, during this kind of inventive process there is a reason, probably, you know, was done -- experimental tests were done in developing this product, which is why 1.8 was chosen. We just did not have that disclosed in our Specification.

JUDGE PRATS: But you do say at page 2 of the Spec, starting at about line 9 I think it is, you do talk about, which you later argued, that

arginine can lead to excess nitric oxide formation, so that -- you do have to have a reason for doing it.

MS. LYNCH: Yes. That is the reason. You know, it provides a physiological benefit to not have a metabolic production of nitric oxide in vivo. So, you know, if we can limit the amounts of arginine that we're providing, we'll reduce the metabolic pathway that will lead to the production of nitric oxide, so that is the reason that we do it. The specific amount of 1.8 is not disclosed, but we do --

JUDGE LEBOVITZ: Well, because I think on that page of the Spec, looks like page 1, it looks like the inventor here is acknowledging that 1 to 3 percent of the total energy intake is preferably provided by arginine. So that actually overlaps.

MS. LYNCH: That was for a different U.S. Patent, so we're discussing prior art there and that -- you know, saying that 1.3 in that patent is what was preferred, and we're saying 3 is too high. We have now done tests, we figured out that you can't have that much arginine in there because it could convert to nitric oxide.

JUDGE LEBOVITZ: Yeah, but it does seem to acknowledge that you could also use less than 3 and 1 to 3, so that does overlap with your range, right?

MS. LYNCH: It does overlap with our range but, as we're claiming here, we need both arginine and proline, so we're going for a synergistic balance of the two. So we've now shown in our Specification that if you use certain amounts of proline that it helps with wound healing. We're also saying we've discovered that it can be, you know, unbeneficial to provide too high amounts. So now we're saying certain amounts of proline and, oh,

by the way, also don't give too much arginine because this could be very bad for the patient.

JUDGE WALSH: The Examiner relied on *McEwen* reference as teaching 1 percent arginine?

MS. LYNCH: Yes, that's correct.

JUDGE WALSH: And I gather you think that was an error, right? Why isn't that appropriate?

MS. LYNCH: We do because the problem here is combining the two references. So you have *Gray* which teaches you cannot give more than this and, in fact, maximize it, and in fact let's give as much as possible with a very minimum of 3. So now the Examiner comes in with *McEwen* and says okay, well, this discloses 1, so let's just combine the two.

We're saying, you know, the minimum amount required by *Gray* is 3, and they're teaching that it has to be at least 3. So you can't just combine two references when one explicitly says don't do that.

JUDGE WALSH: Why not?

MS. LYNCH: Because the Federal Circuit has found that if -- you have to consider the references as a whole and any portion that teaches away has to be considered. So by teaching something that has to be a minimum of 3, it teaches away from something that's less than 3.

JUDGE WALSH: But Federal Circuit also says, though, that the teachings of the various references have to be weighed against each other. Even when one seems to be in contradiction with another, one can fairly weigh the disclosures, so why isn't the Examiner right to listen to *McEwen*?

MS. LYNCH: Because in that effect he's using *McEwen* just for arginine, which Appellants argue teaches away. And in fact, *McEwen*

doesn't even reference proline. So to arrive at the present invention, now we're using *Gray*, which teaches away from *McEwen*, which doesn't even mention proline. And in fact, *McEwen* doesn't give a reason why they use 1 percent arginine. It seems to be entirely random, and for that reason, in addition to teaching away, we would submit that it's not a proper combination of the two references.

JUDGE PRATS: Why isn't *McEwen*'s teaching, that you can use 1 percent arginine, why isn't that at least an obvious to try situation in the KSR sense?

MS. LYNCH: I would say clearly because *Gray* says you can't. So maybe if you had combined *McEwen* with something else, maybe that would make sense. But when *Gray* specifically says don't do this, that to me is a very clear -- you know, if the skilled artisan is reading *Gray*, he's not going to say oh, well, it tells me don't do this because it could -- you know, because you need more than that but, what the heck, I'm going to try something that's significantly less than that.

JUDGE WALSH: Could you point again to the passage where *Gray* says don't use less than --

MS. LYNCH: I'm sorry, perhaps I'm being a little too informal. I didn't mean to say that they say expressly don't do this, but I could point you to a few places in *Gray*. If you look at *Gray*, column 4, lines 54 through 56, they talk about providing a high arginine content. They list a few other amino acids there, but they talk about a high arginine content. And if you go on to column 5, the very top of column 5, it says that the present invention "maximizes the natural available levels or amino acids such as arginine." And then if you look at column 6, lines 60 through 62, it says "Enhanced

wound healing with arginine is believed to be provided at quantities greater than 3 percent of the total calories." So there are several places in *Gray* where they're saying at least 3 percent, preferably greater than that, we're going to maximize that.

So those are the various places in *Gray* where the skilled artisan would say okay, minimum 3.0, but I probably don't want to go anywhere below that. So for that reason, Appellants would say that combining with something that uses 1 percent just doesn't make sense unless you've got the claimed invention in front of you, using a hindsight reconstruction to say well, let's try it anyway, even though *Gray* teaches me not to.

JUDGE LEBOVITZ: So looking at *Gray* alone, because it says at least 3 percent, the obvious to try rationale, at least by *Gray* alone, doesn't work because why would it be obvious to use less when he's pointing you to a upper -- a lower limit that exceeds the limit in the Claim. That would be your position?

MS. LYNCH: Yes, that's exactly right. So maybe, you know, the Examiner could've used a different reference. Like you were saying, why isn't it obvious to try with *McEwen* at 1 percent? Maybe *McEwen* was something else, but the combination of these two specific references just doesn't seem to, you know, combine well, improper.

Those are the main points that I really wanted to hit, so are there any other questions that I could answer for you guys?

JUDGE LEBOVITZ: Any questions?

JUDGE PRATS: No.

JUDGE WALSH: No. Thank you.

MS. LYNCH: Thanks.

JUDGE LEBOVITZ: The hearing is adjourned and we're off the record.

(Whereupon, the proceedings, at 1:29 p.m., were concluded.)